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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,429	10/18/2000	Joseph Tyler	1932.2005-002	4918

21005 7590 07/29/2002

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EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/29/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/691,429

Applicant(s)

TYLER ET AL.

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-23 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 2-18 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 2-23 are pending in the instant application. Acknowledgement is made of Applicant's amendment filed 4/16/02. Claims 19-21 are withdrawn as being drawn to a non-elected invention.

#### ***Allowable Subject Matter***

1. Claim 23 is allowed.

#### ***Response to Amendment***

2. Newly amended claims 19-21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant has included the limitation that the tablet comprise a pharmaceutically active agent, which would have different effects from the originally presented invention, and is not related thereto.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 2-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (U.S. Pat. No. 5,496,545) and John et al. (U.S. Pat. No. 4,302,440).

Holmes-Farley involves an effective amount of a composition containing a phosphate-binding polymer, which may be cross-linked with an agent such as epichlorohydrin (col. 1, line 65- col. 2, line 5). The crosslinking agent is present in an amount ranging from about 0.5% to 75% by weight.

The compositions of Holmes-Farley may be enclosed within a carrier which may be in the form of a container. The compositions can be in the form of tablets. Examples of carriers include methyl cellulose (col. 17, lines 30-45).

John et al. relates to a method for preparing an easily-swallowed, powder-free, gastric disintegrable and thinly coated aspirin tablet. The thin coating, comprising an aqueous spray-coating of hydroxypropyl methylcellulose, has the purposes of: a) greatly improving the ease with which such tablets may be swallowed and b) providing a tablet readily disintegrable in the stomach.

As shown by Holmes-Farley, a tabletted composition consisting of a phosphate-binding polymer and a crosslinking agent would have been known to one with ordinary skill in the art. One with ordinary skill would have known to enclose the composition within a carrier, such carrier consisting of methyl cellulose. Based on the teachings in the art, motivation to use of an aqueous spray-coating of hydroxypropyl methylcellulose

Art Unit: 1616

would have arisen because such coating would have greatly improved the ease of swallowing the tablets and providing a readily disintegrable tablet in the stomach. It is the examiner's viewpoint that such a spray-coating is a carrier for enclosing the composition. Whereas Holmes-Farley does not disclose using 95% of an aliphatic amine polymer, Holmes-Farley teaches that the composition can consist of a combination of a phosphate-binding polymer and a crosslinking agent. The crosslinking agent can be present in an amount of from 0.5% to 75% by weight. It is the examiner's viewpoint that because the tablet is composed of two elements (phosphate-binding polymer and a crosslinking agent) and one of elements (crosslinking agent) is present in an amount of 0.5%, the other element is present in an amount of 99.5% (phosphate binding polymer).

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley, further in view of the instant specification at page 10, lines 7-21.

As stated above, Holmes-Farley teaches an effective composition containing phosphate-binding polymer, which may be cross-linked with an agent such as epichlorohydrin. The composition can be enclosed in a carrier in tablet form. The instant specification teaches that tablet hardness and friability studies, are within the skills of those in the art and are described in the United States Pharmacopeia.

Whereas Holmes-Farley does not teach a tablet comprised of a phosphate-binding polymer crosslinked with epichlorohydrin having a hardness from 150-170N and

Art Unit: 1616

friability of no more than 0.8%, it would have been in the abilities of one with ordinary skill in the art in optimizing the tablet to obtain such a hardness and friability.

### ***Response to Arguments***

5. Based on Applicant's amendments, the previous rejection to claim 4 is withdrawn.

6. In light of Applicant's deletion of claim 1, and amendments to claims 2-8, and 12, the rejection to these claims has been withdrawn.

7. Applicant's arguments filed 4/16/02 have been fully considered but they are not persuasive.

Applicant asserts that the amendment to claim 2, "at least 95% by weight of an aliphatic amine polymer" distinguishes over the previous rejection under 35 U.S.C. 1039(a). This assertion is faulty because Holmes-Farley teach that the composition can consist of a phosphate-binding polymer and a crosslinking agent. The crosslinking agent can be present in an amount of from 0.5% to 75% by weight. It is the examiner's reasoning that because the tablet is composed of two elements (phosphate-binding polymer and a crosslinking agent) and one of elements (crosslinking agent) is present in an amount of 0.5%, the other element is present in an amount of 99.5% (phosphate binding polymer). Thus, claim 2 is still obvious in light of the prior art and the rejection is maintained.

The examiner is in agreement with Applicant's arguments that the PDR reference applied in the previous office action ("Renagel" tablets) is not prior art because it's date

Art Unit: 1616

of publication is after the priority date of the instant application. Therefore, the reference is withdrawn.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

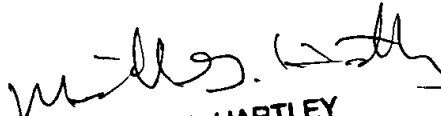
Application/Control Number: 09/691,429

Page 7

Art Unit: 1616

RMD

July 25, 2002

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER